

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY |) | |
| AVERAGE WHOLESALE PRICE |) | |
| LITIGATION |) | MDL No. 1456 |
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| _____ |) | Civil Action No. 01-12257-PBS |
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| THIS DOCUMENT RELATES TO: |) | Judge Patti B. Saris |
| ALL CLASS ACTIONS |) | |
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**SCHERING-PLOUGH CORPORATION'S RESPONSE
TO THE COURT'S ORDER ON PLAINTIFFS' EMERGENCY MOTION
TO COMPEL THE PRODUCTION OF DOCUMENTS AND DATA
UNDERLYING CRIMINAL PLEA AND SETTLEMENT AGREEMENT**

Schering-Plough Corporation ("Schering") respectfully submits this response to the Court's September 29, 2006 Order on Plaintiff's Emergency Motion to Compel the Production of Documents Underlying Criminal Plea and Settlement Agreement.

The Order requires Schering to produce documents underlying the Government's allegations relating to Intron A and Temodar in the Covered Conduct section of the Settlement Agreement between Schering and the United States announced on August 29, 2006 (the "Settlement Agreement," attached hereto as Exhibit A). Schering does not know what acts or omissions – or documents related thereto – underlie the Government's allegations in the Covered Conduct section of the Settlement Agreement relating to Intron A or Temodar because the Government never specified what conduct or documents formed the basis for those allegations. Notwithstanding these facts, and in a good-faith effort to comply with the intent of the Court's order, Schering will produce to Plaintiffs the documents that the Government specifically

identified when previously expressing concerns about the subject matter of the allegations in the Covered Conduct section of the Settlement Agreement, *e.g.*, preceptorships, free drug, etc., relating to Intron-A and Temodar.

In further support of this Response, Schering states the following:

1. On September 29, 2006, the Court ordered that “Schering Plough shall produce any documents relating to pay, remuneration or any benefits paid to doctors relating to Temodar or Intron-A underlying the criminal plea and settlement agreement within 2 weeks.”

2. The allegations by the Government in the Settlement Agreement “relating to pay, remuneration or any benefits paid to doctors relating to Temodar or Intron-A” are included in the civil Settlement Agreement – not the criminal plea – and consist of the following:

- “*The United States contends* that, as part of Schering’s sales and marketing practices for Temodar, from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physician’s practices to induce utilization of Temodar for brain tumors and brain metastases, including for example, *improper preceptorships, advisory boards, entertainment, and placement of clinical studies* in violation of 42 U.S.C. § 1320a-7b(b)(2). Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of false or fraudulent claims for Temodar to the Medicaid and TRICARE Programs and caused the DVA to purchase Temodar by providing physicians and physician’s practices with illegal remuneration to induce them to prescribe Temodar for Patients.” Settlement Agreement ¶ II.H(vi) (emphasis added).
- “*The United States contends* that, as part of Schering’s sales and marketing practices for superficial bladder cancer from September 1999 through December 2003, Schering knowingly and willfully offered and paid various forms of illegal remuneration to physicians and physician’s practices to induce the utilization of Intron A for superficial bladder cancer including, for example, *improper preceptorships, advisory boards, entertainment, and placement of clinical studies* in violation of 42 U.S.C. § 1320a-7b(b)(2), and encouragement of improper billing by physicians of Intron A vial overfill and free drugs. The Government further contends that Schering promoted Intron A for superficial bladder cancer although Schering did not have approval from the FDA for use in that indication. Furthermore, the Government contends that, during this time period, Schering knowingly caused the submission of

false or fraudulent claims to the Medicaid, Medicare, and TRICARE Programs for Intron A and caused the DVA to purchase Intron A by inducing physicians and physicians to prescribed it to patients with superficial bladder cancer by providing them with such illegal remuneration.” *Id.* ¶ II.H(viii) (emphasis added).

3. Schering did not admit that these or any assertions of fact or liability by the Government as part of the civil settlement were true. Settlement Agreement ¶ II.J.

4. As recited in the Settlement Agreement, Schering resolved these allegations by the Government “to avoid the delay, expense, inconvenience, and uncertainty of protracted litigation” *Id.* ¶ II.K.

5. During the course of an investigation lasting several years, Schering produced millions of pages of documents, on a variety of subjects. During the discussions concerning the terms of the Settlement Agreement, the Government never identified specific acts or omissions by the company – or the documents relating thereto – underlying its allegations in the Covered Conduct section of the Settlement Agreement relating to Intron A and Temodar. Specifically, Schering does not know, and the Government did not identify, which particular documents relating to “preceptorships, advisory boards, entertainment, and placement of clinical studies” underlie the Covered Conduct section of the Settlement Agreement. Similarly, Schering does not know, and the Government did not identify, specific documents relating to the “encouragement of improper billing by physicians of Intron A vial overfill and free drugs.” Such information – if it exists – would be solely within the possession of the Government.

6. Notwithstanding Schering’s lack of specific knowledge, Schering has made a good-faith effort to comply with the intent of the Court’s Order. Over the course of more than three years, Schering and the Government participated in many meetings and presentations regarding the Government’s investigation. During those meetings, the Government specifically

identified certain documents that relate to the broad categories of Covered Conduct in the civil Settlement Agreement involving Intron-A and Temodar. Schering will produce today all of the documents identified by the Government during those meetings under separate cover to Plaintiffs.

7. Schering further represents that it has previously produced – subject to certain objections and the resolution of certain other objections by mutual agreement with Plaintiffs – all non-privileged documents which, to its knowledge, are responsive to the following requests by Plaintiffs:

- “All documents relating to the use or provision of free samples, educational grants, marketing grants, and payment for specific data gathering, financial incentive, or other incentive to induce purchases of any AWPID during the Relevant Time Period.” Pls.' Omnibus Requests for Production and Interrogatories (Mar. 31, 2004) ("Pls.' Omnibus Request") No. 37.
- “All documents relating to any communication with doctors, other health care professionals, or any person or entity providing health care services to seek Medicare reimbursement or consumer co-payment for free samples of each AWPID you provided to them.” Pls.' Omnibus Request No. 54.
- “All documents concerning your contractual relationships with wholesalers, independent practice association, pharmacies or providers insofar as they cover subject drugs, including, without limitation, master agreements, addenda, schedules, attachments, requests for proposal, responses to requests for proposal and correspondence.” Pls.' Omnibus Request No. 70.
- "All documents produced by you, whether voluntarily or involuntar[il]y, in any governmental investigation or inquiry concerning the use of AWP." Pls.' Omnibus Request No. 9.
- "All documents relating to or reflecting any payments you gave to providers relating to any AWPID." Pls.' Omnibus Request No. 41.

Respectfully Submitted,

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Dated: October 11, 2006

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Eric P. Christofferson
Eric P. Christofferson